

Version with Markings to Show Changes Made

In the Claims

1. (AMENDED) A rapidly disintegrable solid preparation **having no roughness and improved chalky taste** which comprises (i) a pharmacologically active ingredient, (ii) a sugar and (iii) a low-substituted hydroxypropylcellulose having 5% by weight or more to less than 7% by weight of hydroxypropoxyl group.

9. (AMENDED) A [preparation of Claim 1, wherein the pharmacologically active ingredient is] **rapidly disintegrable solid preparation which comprises (a) voglibose, (ii) a sugar and (iii) a low-substituted hydroxypropylcellulose having 5% by weight or more to less than 7% by weight of hydroxypropoxyl groups.**

18. (TWICE AMENDED) A method for preparing a rapidly disintegrable solid preparation **having no roughness and improved chalky taste** comprising combining a low-substituted hydroxypropyl cellulose having 5% to less than 7% by weight of hydroxypropoxyl groups, a pharmacologically active ingredient and a sugar.

19. (TWICE AMENDED) A method for improving [fast disintegrability of] a solid preparation comprising combining a pharmacologically active ingredient and a sugar with a low-substituted hydroxypropylcellulose having 5% by weight or more to less than 7% by weight of hydroxypropoxyl groups **to form a solid preparation, wherein said preparation has no roughness and improved chalky taste.**

REMARKS

I. Amendments

By this amendment, claims 1, 9, 18 and 19 have been amended.

This amendment adds no new matter to the specification. Support for this amendment is found in the specification and claims as filed.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "Version with Markings to Show Changes Made".

No amendment of inventorship is necessitated by this amendment.

II. Discussion of the Obviousness-Type Double Patenting Rejection

Claim 20 has been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 18 and 19 of co-pending U.S. Patent Application Serial No. 09/403,429.

A Terminal Disclaimer over the co-pending patent application accompanies this response. Therefore, Applicants respectfully request withdrawal of the obviousness-type double patenting rejection.

III. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Ohno *et al.* in view of Shimizu *et al.*

Claims 10-12, 18 and 20 have been rejected as obvious over Ohno *et al.*, U.S. Patent No. 5,958,453, in view of Shimizu *et al.*, U.S. Patent No. 6,299,904.

A Certified Copy of the English-language translation of the priority document of the present invention accompanies this response. Applicants respectfully request that the Examiner reconsider the cited '904 reference in light of Applicants' priority, perfected by the submission of the translation.

IV. Discussion of the Rejection under 35 U.S.C. Sec. 102(b) over Ohno *et al.*

The rejection of claims 1-7, 9 and 13-17 under 35 U.S.C. Sec. 102(b) as anticipated by Ohno *et al.* (U.S. Patent No. 5,958,453) has been maintained.

By this amendment, independent claims 1, 18 and 19 have been amended to include the limitation of “no roughness and improved chalky taste” of the preparation formed. This amendment adds no new matter to the specification. Support for the amendment may be found *inter alia* at page 2, line 4; page 42, lines 1 and 2; page 42, line 14 and page 45, line 6.

The cited reference does not indicate that preparations formed as disclosed therein would have no roughness and improved chalky taste, as indicated in claims 1, 18 and 19 as amended. Therefore, Applicants submit that their invention is not anticipated by the cited reference.

Furthermore, by this amendment, Applicants have re-written claim 9 as an independent claim. Claim 9 specifies an active ingredient which is not disclosed by the cited reference, and therefore Applicants believe that this claim is free of the cited art, especially in light of the fact that claims 10-12, which also specify certain active ingredients, have already been found to be free of the cited art by the Examiner.

Claims 2-7 and 13-17 depend upon claim 1. Applicants submit that the more specific dependent claims are not anticipated for the same reason that independent claim 1 as amended is not anticipated by the cited reference.

Therefore Applicants respectfully request withdrawal of the Sec. 102(b) rejection over Ohno *et al.*

V. Discussion of the Rejection under 35 U.S.C. §103(a) over Ohno *et al.* in view of Shashoua *et al.*

The rejection of claims 1-7 and 9-19 under 35 U.S.C. Sec. 103(a) for obviousness over the Ohno *et al.*, U.S. Patent No. 5,958,453 in view of Shashoua *et al.*, U.S. Patent No. 5,795,909 has been maintained. Applicants disagree for two reasons: 1) there is no motivation to combine the two cited references and 2) the present claims, as amended, are not rendered obvious by the combination of the cited art.

To elaborate upon their first assertion, Applicants submit that there is no motivation for combining the two cited references merely because both refer to active ingredients and oral dosage forms. The '453 reference is directed to buccal preparations for fast disintegratability and dissolubility. In contrast, the '909 reference indicates that appropriate delivery systems include "time-release, delayed release or sustained release delivery systems" at col. 49, lines 62 and 63; and further that "long-term sustained release implants may also be used" at col. 50, line 11. There would be no motivation on the part of one skilled in the art of formulation to look to a reference disclosing slow release formulations when designing a formulation for very rapid release.

To elaborate upon their second assertion, by this amendment, independent claims 1, 18 and 19 have been amended to include the limitation of "no roughness and improved chalky taste" of the preparation formed. As Applicants have argued in Section IV above, the '453 reference does not teach or suggest preparations having no roughness and improved chalky taste. The deficiencies of Ohno *et al.* are not cured by Shashoua *et al.*

Moreover, by this amendment, claim 9 has been made independent. Applicants did not find the active ingredient of claim 9 among the active ingredients listed in the cited reference. Applicants respectfully request that the Examiner indicate where the active ingredient of claim 9 is found in the cited reference.

Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 103(a) over Ohno *et al.*, U.S. Patent No. 5,958,453 in view of Shashoua *et al.*, U.S. Patent No. 5,795,909.

VI. Conclusion

Reconsideration of the claims as amended in view of the arguments made above is solicited. Early allowance of the claims is requested. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, she is respectfully requested to call Applicants' attorney.

Respectfully submitted,

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